

410-124-063 CRITERIA AND CONTRAINDICATIONS FOR HEART-LUNG TRANSPLANTS

1. The client must have a maximum probability of a successful clinical outcome, i.e., the probability of the client's survival for a period of five years or more subsequent to the transplant must be at least 25 percent.
2. Coverage for transplantation is based on the OHP Prioritized List of Health Services.
3. A client considered for a heart-lung transplant must have one of the following diagnoses:
 - (a) Eisenmenger's Syndrome,
 - (b) Cystic Fibrosis,
 - (c) Primary pulmonary hypertension, or
 - (d) Emphysema - Contact OMAP for prior authorization and payment, even when the client is in a managed health care plan.
4. A client considered for a heart-lung transplant must have cardio-pulmonary failure with a poor prognosis, i.e., less than a 50% chance of survival for 18 months without a transplant as a result of poor cardiac functional status or cardiac/pulmonary functional status.
5. All alternative medically accepted treatments that have a one year survival rate comparable to that of heart-lung transplantation must have been tried or considered.
6. Requests for transplant services for children suffering from early cardio-pulmonary disease may be approved before attempting alternative treatments if medical evidence suggests an early date of transplant is likely to improve the outcome.
7. A client with one or more of the following contraindications is ineligible for heart-lung transplant services:
 - (a) untreatable systemic vasculitis,
 - (b) incurable malignancy,
 - (c) diabetes with end-organ damage,
 - (d) active infection which will interfere with the client's recovery,
 - (e) refractory bone marrow insufficiency,

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- (f) irreversible renal disease,
 - (g) irreversible hepatic disease,
 - (h) HIV positive test results.
8. The following **may be considered contraindications** to the extent that the evaluating transplant center and/or the specialist who completed the comprehensive evaluation of the client believe the following condition(s) may interfere significantly with the recovery process:
- (a) hyperlipoproteinemia,
 - (b) curable malignancy,
 - (c) significant cerebro-, or peripheral vascular disease,
 - (d) unresolved or continuing thromboembolic disease or pulmonary infarction,
 - (e) serious psychological disorders,
 - (f) drug or alcohol abuse.

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410-124-065 CRITERIA AND CONTRAINDICATIONS FOR SINGLE LUNG TRANSPLANTS

1. The client must have a maximum probability of a successful clinical outcome, i.e., the probability of the client's survival for a period of five years or more subsequent to the transplant must be at least 25 percent.
2. Coverage for transplantation is based on the OHP Prioritized List of Health Services.
3. A client considered for a single lung transplant must have one of the following diagnoses:
 - (a) Fibrotic lung disease,
 - (b) Pulmonary hypertension with reversible RV function,
 - (c) Alpha 1-antitrypsin deficiency,
 - (d) Eisenmenger's Syndrome with correctable intracardiac defect and recoverable RV function, or
 - (e) Emphysema - Contact OMAP for prior authorization and payment, even when the client is in a managed health care plan.
4. The client must have a poor prognosis, i.e., less than a 50% chance of survival for 18 months without a transplant as a result of poor pulmonary functional status.
5. All alternative medically accepted treatments that have a one year survival rate comparable to that of single lung transplantation must have been tried or considered.
6. Requests for transplant services for children suffering from early cardio-pulmonary disease may be approved before attempting alternative treatments if medical evidence suggests an early date of transplant is likely to improve the outcome.
7. A client with one or more of the following contraindications is ineligible for single lung transplant services:
 - (a) untreatable systemic vasculitis,
 - (b) incurable malignancy,
 - (c) diabetes with end-organ damage,
 - (d) active infection which will interfere with the client's recovery,

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- (e) refractory bone marrow insufficiency,
 - (f) irreversible renal disease,
 - (g) irreversible hepatic disease,
 - (h) HIV positive test results.
8. The following **may be considered contraindications** to the extent that the evaluating transplant center and/or the specialist who completed the comprehensive evaluation of the client believe the following condition(s) may interfere significantly with the recovery process:
- (a) hyperlipoproteinemia,
 - (b) curable malignancy,
 - (c) significant cerebro-, or peripheral vascular disease,
 - (d) unresolved or continuing thromboembolic disease or pulmonary infarction,
 - (e) serious psychological disorders,
 - (f) drug or alcohol abuse.

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410-124-070 CRITERIA AND CONTRAINDICATIONS FOR BILATERAL LUNG TRANSPLANTS

1. The client must have a maximum probability of a successful clinical outcome, i.e., the probability of the client's survival for a period of five years or more subsequent to the transplant must be at least 25 percent.
2. Coverage for transplantation is based on the OHP Prioritized List of Health Services.
3. A client considered for a bilateral lung transplant must have one of the following diagnoses:
 - (a) Fibrotic lung disease,
 - (b) Alpha 1-antitrypsin deficiency,
 - (c) Pulmonary hypertension with reversible RV function,
 - (d) Eisenmenger's Syndrome with correctable intracardiac defect and recoverable RV function,
 - (e) Cystic Fibrosis, or
 - (f) Emphysema - Contact OMAP for prior authorization and payment, even when the client is in a managed health care plan.
4. The client must have a poor prognosis, i.e., less than a 50% chance of survival for 18 months without a transplant as a result of poor pulmonary functional status.
5. All alternative medically accepted treatments that have a one year survival rate comparable to that of bilateral lung transplantation must have been tried or considered.
6. Requests for transplant services for children suffering from early cardio-pulmonary disease may be approved before attempting alternative treatments if medical evidence suggests an early date of transplant is likely to improve the outcome.
7. A client with one or more of the following contraindications is ineligible for bilateral lung transplant services:
 - (a) untreatable systemic vasculitis,
 - (b) incurable malignancy,
 - (c) diabetes with end-organ damage,

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- (d) active infection which will interfere with the client's recovery,
 - (e) refractory bone marrow insufficiency,
 - (f) irreversible renal disease,
 - (g) irreversible hepatic disease,
 - (h) HIV positive test results.
8. The following **may be considered contraindications** to the extent that the evaluating transplant center and/or the specialist who completed the comprehensive evaluation of the client believe the following condition(s) may interfere significantly with the recovery process:
- (a) hyperlipoproteinemia,
 - (b) curable malignancy,
 - (c) significant cerebro-, or peripheral vascular disease,
 - (d) unresolved or continuing thromboembolic disease or pulmonary infarction,
 - (e) serious psychological disorders,
 - (f) drug or alcohol abuse.

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410-124-080 CRITERIA AND CONTRAINDICATIONS FOR BONE MARROW, PERIPHERAL STEM CELL AND ALLOGENEIC CORD BLOOD TRANSPLANTS AND FOR THE HARVESTING OF AUTOLOGOUS BONE MARROW AND PERIPHERAL STEM CELL TRANSPLANTS

1. For autologous or allogeneic bone marrow or peripheral stem cell transplants, the client must have one of the following diagnoses:
 - (a) Acute lymphocytic leukemia,
 - (b) Acute non-lymphocytic leukemia (i.e., myeloid, monocytic or megakaryocytic leukemia),
 - (c) Hodgkin's disease,
 - (d) Non-Hodgkin's lymphoma,
 - (e) Neuroblastoma, treatable (high risk Stage III or IV),
 - (f) Lymphoid leukemias other than acute lymphocytic leukemia,
 - (g) Multiple myeloma and chronic leukemias,
 - (h) Relapsed Wilms' tumor non-responsive to standard therapies, with minimal tumor burden, and where autologous bone marrow transplant is intended to cure,
 - (i) Ewing's Sarcoma
2. The following diagnoses are appropriate only for allogeneic bone marrow, allogeneic peripheral stem cell and allogeneic cord blood transplants:
 - (a) Aplastic anemia,
 - (b) Agranulocytosis,
 - (c) Other genetic defects for which bone marrow transplantation has been successful, such as:
 - (1) thalassemia and hemoglobinopathies (e.g., sickle cell),
 - (2) osteopetrosis,
 - (3) Wiskott-Aldrich syndrome,
 - (4) severe combined immunodeficiency (SCID),
 - (5) inborn errors of metabolism, and

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- (d) Myelodysplastic syndrome,
 - (e) Constitutional aplastic anemias (i.e., Fanconi's anemia),
 - (f) chronic myelogenous leukemia.
3. Peripheral stem cell (buffy coat) transplants are covered for all leukemias only when:
- (a) there is early relapse post allogeneic bone marrow transplant, and
 - (b) peripheral stem cells are from the original allogeneic donor.
4. Coverage for transplantation is based on the OHP Prioritized List of Health Services.
5. Authorization for payment for transplants will be approved only when the following conditions are also met:
- (a) The following criteria will be used to evaluate the prior authorization request for all bone marrow transplants:
 - (1) Transplantation must be the most effective medical treatment, when compared to other alternatives, in prolonging life expectancy to a reasonable degree.
 - (2) The client must have a maximum probability of a successful clinical outcome and the expectation of not less than a 10% five year survival; that is, treatment by bone marrow transplantation must have been shown to be an effective treatment (survival of five or more years) considering each of the following factors:
 - (A) the type of transplant, i.e., autologous or allogeneic;
 - (B) the specific diagnosis of the individual;
 - (C) the stage of illness, e.g., in remission, not in remission, in second remission;
 - (D) satisfactory antigen match between donor and recipient in allogeneic transplants.
 - (3) All alternative treatments with a one year survival rate comparable to that of bone marrow transplantation must have been tried or considered.
 - (b) Allogeneic transplants will be approved for payment only when there is a minimum of 5-out-of-6 antigen match for bone marrow and peripheral stem cell transplants, or 4-out-of-6 match for cord blood transplants, considering the HLA-A, B, and DR loci. Donor search costs up to an amount of \$15,000 will be covered only if donor search is prior authorized.

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- (c) Autologous transplants (bone marrow and peripheral stem cell) will be approved for payment if:
- (1) The client has one of the conditions listed in subsection 1 of this rule, and
 - (2) Documentation in the current peer-reviewed medical literature indicates that the disease is potentially curable when an autologous bone marrow transplant or peripheral stem cell transplant is performed in conjunction with:
 - (A) total body radiation; and/or
 - (B) high dose chemotherapy.
 - (3) The client has no other contraindications for bone marrow transplant or peripheral stem cell reinfusion.
- (d) The harvesting and storage of autologous bone marrow and autologous peripheral stem cell collection alone will be approved for payment under the following conditions:
- (1) The client has had one of the conditions listed in 1 of this rule, and
 - (2) The client's marrow meets the clinical standards of remission at the time of storage, and
 - (3) A board certified hematologist/oncologist with specific experience in bone marrow transplant (BMT) services (e.g., cryopreservation and immunosuppressive treatment) has recommended the storage of autologous bone marrow or peripheral stem cell collection for a possible future transplant/reinfusion.
 - (4) The client has no other contraindications for bone marrow transplant/peripheral stem cell reinfusion.
6. The following are contraindications for bone marrow, peripheral stem cell and cord blood transplants and for the harvesting of autologous bone marrow or peripheral stem cell collection:
- (a) Incurable malignancy.
 - (b) Irreversible terminal state (moribund or on life support).
 - (c) An irreversible disease of any other major organ system likely to limit life expectancy to five years or less.
 - (d) Positive HIV test results.

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7. The following may be considered contraindications to the extent the evaluating transplant center and/or the specialist who completed the comprehensive evaluation of the client believe these condition(s) may interfere significantly with the recovery process:
- (a) Serious psychological disorders,
 - (b) Alcohol or drug abuse.
8. Prior authorization for harvesting of autologous bone marrow or peripheral stem cells does not guarantee reimbursement for the transplant; the patient must meet the criteria specified above and in 410-124-020 at the time the transplant is performed.

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